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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,991	MCGEE ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Declaration and the Response, both received by the Office on June 6, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 22 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent 5,213,811 to Frisbee *et al.* in view of US Patent4,663,318 to Davis.

Frisbee *et al.* disclose sugar beads coated with a first coating including a drug and hydroxypropylmethyl cellulose, a second coating including ethylcellulose and a plasticizer, and an additional coating of the drug and hydroxypropyl methyl cellulose. Frisbee *et al.* teach that their compositions provides initial rapid release of the drug, followed by sustained release of the drug as the composition passes through the gastrointestinal tract (c 1, l 63 – c 2, l 31). Additionally, Frisbee *et al.* teach that coated particles can be used to fill a capsule, thereby making a pharmaceutical dosage form (c 2, l 32-34). Frisbee *et al.* further teach that the active agent can be any drug with a solubility of at least 5% by weight in gastric fluid and less than 1% by weight in intestinal fluid.

Frisbee *et al.* does not specifically teach the inclusion of galanthamine in their disclosure. However, although the reference only exemplifies one active agent, they teach that the composition can be used and applied to many other active agents. It is the position of the examiner that when a new formulation or dosage form is discovered it is readily applied to different types of active ingredients. It would be burdensome for the inventor of the new type of dosage form to disclose examples regarding each and every potentially useful active agent. Additionally, looking to the known art for galanthamine, there are no specific guidelines as to how to prepare a dosage form of the drug. For example, Davis teaches galanthamine for the treatment of Alzheimer's disease. In his disclosure, Davis teaches that galanthamine can be administered through solid oral formulations, such as tablets and capsules. Davis further teaches that the tablets and capsules should be prepared by known tablet and capsule making techniques (c 2, l 20-44). Therefore, it is the position of the examiner that one of ordinary skill in the art would look to the art regarding pharmaceutical dosage forms to determine an appropriate dosage form for the administration of galanthamine. It is the position of the examiner that Frisbee is one of these such disclosures. Lastly, the burden is shifted to applicant to provide evidence as to why galantamine would not be obvious to use in the dosage form of Frisbee *et al.* If there are chemical or practical reasons making the above combination unobvious, applicant is invited to provide evidence to support this.

Frisbee *et al.* do not disclose applicant's specific plasticizers to be used in combination with ethylcellulose. Frisbee *et al.* teach the use of diacetylated monoglycerides and triacetin. However, in other areas of their disclosure, Frisbee *et al.* teach that triethyl citrate and diethyl phthalate are also acceptable plasticizers. It would have been obvious to one having ordinary

skill in the art at the time the invention was made to use triethyl citrate or diethyl phthalate along with ethylcellulose for its art intended purpose. The selected of a known material based on its suability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Claims 23-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Frisbee *et al.*, in view of Davis, as discussed above, and further in view of WO 98/22072 to Willson.

Frisbee *et al.* in view of Davis are discussed above as teaching a novel dosage form, comprising multicoated particles, wherein it would be obvious to use galanthamine as the active agent. Davis also teaches that it is known to administer tablets of capsule containing 5, 10, and 25 mg of galanthamine hydrobromide to be taken four times a day, or a sustained release preparation delivering an equivalent daily dose.

Frisbee *et al.* in view of Davis. fail to teach a pharmaceutical package comprising a container, a formulation and written matter.

Willson is relied for the teaching that individually separated dosage form packaging is known in the art. Willson discloses a pharmaceutical package for aiding or increasing patient compliance for the administration of a pharmaceutical drug regimen, comprising at least one blister card, wherein each blister card comprises the total daily dose of the pharmaceutical, and wherein each dose section comprises an indicia denoting the time in which the dose is to be administered, as well as a patient information booklet comprising dosing information, side effect information, and patient incentive information (abstract).

Additionally, due to the teachings of Davis, which teaches administration of a particular amount of active daily, it would have been obvious to one of ordinary skill in the art to package the dosage forms in a system such as that described by Willson. The motivation lies in the teachings and advantages of the Willson system. Additionally, galathamine is used for the treatment of Alzheimer's, where reminders, and additional help in the administration of an active agent would be enormously helpful. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive.

Applicant argues that Frisbee requires a three polymer coating, among which is ethylcellulose, while the instant claims require only a one polymer coating. The examiner is not persuaded by this argument for several reasons. First, claim 1 as written requires only that the particles be coated by a release rate controlling membrane coating. The claim does not recite what this coating is made of, or that the coating contains only one polymer. Furthermore, not until claim 3 is a polymer even mentioned, and in that claim a film forming polymer is mentioned as the water soluble excipient. Still nothing has been specified regarding the rate controlling membrane coating. In claim 10, Applicant's recite that the release rate controlling membrane coating comprises a water insoluble polymer, and in claim 11, ethylcellulose is mentioned as the specific polymer. However, as stated previously, these specific limitations are not found in the generic claims, and in fact are not found in the majority of the instant claims. Therefore, these specifics are not read into all of the claims.

Second, Applicant has drafted the claims using "comprising" language. Comprising language in the claims allows for other components to be present in the composition. The expression "comprising" permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts . *See Moleculon Research Corporation v CBS , Inc 229 USPQ 805 ; In re Baxter 210 USPQ 795, 803* . Therefore, there is nothing in the instant claims which prohibits the presence of more than one polymer.

Third, Applicant himself has allowed for the presence of more than one polymer. The claims teach one polymer as a water soluble excipient, and another polymer as a component in the release rate controlling membrane. For these reasons, the argument that Frisbee requires three polymers is not found to be persuasive.

Applicant also argues that there is no teaching that ethylcellulose alone can accomplish sustained release of galantamine. This argument is moot for the reasons stated above. There is nothing in the instant claims which requires ethylcellulose to be the only polymer used in the formulation.

Applicant also argues that there are many elements in the claims which have not been considered. Applicant first points to the limitations of claim 15. The examiner has supplied a combination of references which she believes renders the claims obvious. Regarding the particular release rates, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to

establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The examiner shifts the burden to Applicant to provide comparative data showing that the release rate of the above combination would differ from the release rate claimed by Applicant.

Applicant also asserts that the examiner has not considered the limitations of claims 23, 24, and 25. The examiner respectfully disagrees and points to the rejection found below. This rejection combines the teachings of Frisbee, Davis, and Willson. Willson, as stated below, is relied upon for the teaching that individually separate dosage form packaging is known in the pharmaceutical art. Applicant has provided no evidence why this known form of packaging would be novel when taken with this particular formulation. The examiner maintains that using a known form of packaging, such as that described by Willson, and using it with a known formulation, does not render patentability to the claims.

For the above listed reasons, the rejections are maintained and made final.

Discussion of Declaration

The declaration is not found to be persuasive for several reasons. First, for a declaration to be considered persuasive, it must be commensurate in scope with the instant claims. However, Applicant provides no discussion in the declaration of the particular formulation used. Was there one specific formulation that was used for all of the testing? If so, what were the components of this formulation? If the formulation is more specific than claim 1, then the declaration is not persuasive for claim 1.

Additionally, the examiner notes that Applicant has compared the controlled release formulation to the immediate release formulation. However, the examiner has not relied on the immediate release formulation in writing the rejection. Therefore, these comparisons are moot with respect to the examiner's rejections.

For these reasons, the declaration is not found to render patentability to the instant claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A.E. Pulliam
Patent Examiner
August 15, 2003

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